# Reagan-Udall Foundation for the Food and Drug Administration

The Reagan-Udall Foundation (RUF) for the FDA is an independent nonprofit corporation located in the District of Columbia. RUF was created by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA) "to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety."

RUF embodies FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century. Pursuant to the unique, statutory relationship between RUF and FDA, the central focus of RUF is to assist in the creation of new, applied scientific knowledge, tools, standards and approaches the FDA needs to evaluate products more effectively, predictably and efficiently, and thereby enhance the agency's ability to protect and promote the health of the American public. To accomplish this critical task, the foundation will:

- spearhead complex research collaborations involving public and private partners,
- ensure broad-based participation (including consumer perspectives),
- ensure that new knowledge gained from the collaboration is in the public domain;
- help train a new generation of regulatory scientists; and
- leverage outside resources for these activities

## RUF's Governance and Authorities

The Foundation is governed by a 14-member board of directors that currently includes members from academia, consumer groups, the medical product and food industries, health care providers, and others. The FDA Commissioner and the Director of the National Institutes of Health serve as non-voting members of the Board. The statute prohibits government control of the foundation, and gives RUF no role in FDA's regulatory process.

The law also includes significant provisions to assure RUF's transparency and public accountability. For example, RUF bylaws must be made public; the foundation must make annual reports of its activities to Congress; and it must abide by specific rules to prevent conflicts of interest. To strengthen these protections, the RUF's board of directors has added further requirements to promote transparency and prevent undue influence, including requiring public disclosure of gift-acceptance policies and decisions, public disclosure of all projects and funding sources, and project-specific policies on conflicts of interest.

## Current Activities

At the beginning of 2012, FDA is working with RUF on two exciting scientific collaborations, with several other projects on the near horizon.

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Already in progress are:

- *Development of new tuberculosis drug regimens*
  RUF is serving as a neutral convener to organize the regulatory science research components of a broad effort by the Bill & Melinda Gates Foundation to develop new drug regimens to treat TB. RUF is bringing together a diverse and international group of scientists, regulators, academics, and drug developers to develop the most effective methodologies for evaluating the new treatments.

- *Systems Toxicology Pilot Study*
  RUF, with help in kind from the Friends of Cancer Research, is spearheading an effort to improve the safety of an important class of anti-cancer therapies, the tyrosine kinase inhibitors. This effort brings together a group of 40 experts from the federal government, industry, and academia, as well as leaders from private foundations and the patient advocacy community.

In addition, RUF is:

- Developing a fellowship program to bring targeted scientific expertise into the FDA and
- Planning a public-private collaboration to advance the science and tools necessary for generating better and more useful postmarket medical evidence about FDA-regulated medical products.